

REMARKS

Upon entry of the foregoing amendment, claims 16-34 are pending in the application. Claims 1-15 have been canceled, claims 19-20 are currently amended and claims 21-34 have been added.

Applicant respectfully requests entry of the above amendment and submits that the above amendment does not constitute new matter. Support for the amended claims can be found throughout the specification and in the claims as originally filed. In particular, support for newly added claims 21-34 can be found in claims 1-20 as originally filed and in the specification on pages 6-7, paragraphs [19]-[23]. Claims 19 and 20 have been amended to conform with U.S. practice.

Response to Restriction Requirement

The Office Action required restriction to one of Groups I-III, provided *infra*, which are purportedly distinct inventions under 35 U.S.C. § 121. The Office Action requires that Applicants elect one of the following three (3) allegedly distinct inventions:

I. Claims 1-15, drawn to a promoter which contains Cofilin as an active ingredient, classified in class 530, subclass 350.

II. Claims 16-18, drawn to a method of promoting growth, differentiation of hematopoietic stem cells comprising administering Cofilin, classified in class 514, subclass 12.

III. Claims 19-20, drawn to a method of regenerative medicine and a method of expanding hematopoietic cells *ex vivo* by using Cofilin, classified in class 435, subclass 325.

Applicants hereby provisionally elect Group II, which covers claims 16-18, drawn to, according to the Office Action, a method of promoting growth, differentiation of hematopoietic stem cells comprising administering Cofilin, **with traverse**, and respectfully request reconsideration of the restriction requirement in view of the following remarks. Furthermore, Applicants submit that new claims 21-34, which depend directly or indirectly from claim 16 or 17, fall within Group II and thus Applicants' election of Group II encompasses all of claims 16-18 and 21-34. Claims 21-34 are presented in the amendment filed in this response. Applicants moreover reserve the right to file divisional application(s) directed to non-elected subject matter.

Applicants respectfully urge that the Restriction Requirement is improper, as it does not establish that searching all the inventions would constitute an undue burden on the Patent Office.

Accordingly, Applicants submit that the Restriction Requirement is improper and should be withdrawn or at least modified.

According to the MPEP, when claims can be examined together without undue burden, the USPTO must examine the claims on the merits even though they are directed to independent and distinct inventions. *See* MPEP at § 803. In establishing that an “undue burden” would exist for co-examination of claims, the USPTO must show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the USPTO must show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search. *See* MPEP at § 808.02.

Applicants submit that it would not constitute an undue burden to examine the inventions of Groups II and III together. The inventions of Groups II and III, while patentably distinct from each other, are related to each other by subject matter. The search within each of Groups II and III would overlap because Groups II and III both encompass methods involving administering or using at least one promoter of growth, differentiation of hematopoietic stem cells, hematopoietic progenitors, or a combination thereof, wherein said at least one promoter contains Cofilin as an active ingredient. For example, Group II requires administering at least one promoter of growth, differentiation of hematopoietic stem cells, hematopoietic progenitors, or a combination thereof, and Group III requires using at least one promoter of growth, differentiation of hematopoietic stem cells, hematopoietic progenitors, or a combination thereof. A search of the administration or use of at least one promoter of growth, differentiation of hematopoietic stem cells, hematopoietic progenitors, or a combination thereof would necessarily be conducted in the same field of search. Indeed, the methods of Groups II and III both require at least one promoter that contains Cofilin as an active ingredient which involves the growth, differentiation of hematopoietic stem cells, hematopoietic progenitors, or a combination thereof. Accordingly, it would not constitute an undue burden to search the methods of Groups II and III together.

Applicants further submit that it would not constitute an undue burden to examine the inventions of Groups II and III together in light of newly added claim 34, for example, which Applicants submit falls within Group II. Claim 34 is drawn to the method of claim 16 or 17, wherein said promoter can be used in regenerative medicine. As stated in the specification, “If the present promoters of the growth and/or differentiation of hematopoietic stem cells and/or hematopoietic progenitors are to be used in regenerative medicine, they are either administered *in*

vivo as described above or added *ex vivo* to a culture medium.” (See page 20, paragraph [69]). Thus, a search of claim 34 (Group II), which requires that the promoter can be used in regenerative medicine, would necessarily include the search of the administration of the promoter *in vivo* or *ex vivo*. It is noted, Group III is drawn to methods of expanding hematopoietic stem cells *ex vivo*, in methods including a method of regenerative medicine. Accordingly, because Groups II and III both involve the administration or use of at least one promoter that contains Cofilin, *in vivo* or *ex vivo*, in methods including a method of regenerative medicine, it would not constitute an undue burden to search the methods of Groups II and III together.

Applicants further submit that it would not constitute an undue burden to examine the inventions of Group I-III together. However, in the interest in expediting prosecution, Applicants have canceled claims 1-15 (Group I). Applicants reserve the right to file a divisional application directed to the claims of Group I.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all claims be allowed to be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicants reaffirm the election with traverse of claims 16-18 and 21-34 (Group II).

CONCLUSION

Applicants respectfully request entry of the above claim amendments.

In view of the above amendment and remarks, early notification of a favorable consideration is respectfully requested.

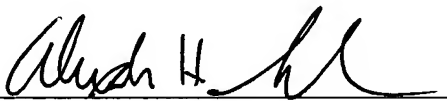
If the Examiner believes that the prosecution might be advanced by discussing the application with Applicants' representatives, in person or over the telephone, we would welcome the opportunity to do so.

A check is enclosed in the amount of \$1,020.00, which covers the three-month extension of time fee. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

Dated: March 29, 2005

By:



Robert M. Schulman
Registration No. 31, 196

Alexander H. Spiegler
Registration No. 56,625

HUNTON & WILLIAMS LLP
Intellectual Property Department
1900 K Street, N.W., Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

RMS/AHS:sac